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10/027,080	12/20/2001	John Laurence Minck JR.	267/166	9793

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

17

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,080

Applicant(s)

MINCK ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6, 14-18, 20 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,605,101 to Schaefer et al.

Regarding claims 1 and 15, Schaefer discloses a member having a length, at least a portion of the length having a planar serpentine shape when the member is in a relaxed condition (FIG. 5), wherein at least a portion of the serpentine shape comprises a curvilinear segment having a non-uniform curvature.

Regarding claims 2 and 16, Schaefer discloses that the member comprises a coil (microcoil 22).

Regarding claims 3 and 17, Schaefer discloses that substantially all of the length of the member has a serpentine shape when the member is in a relaxed condition (FIG. 5).

Regarding claims 4 and 18, Schaefer discloses that a distal portion of the member has a serpentine shape when the member is in a relaxed condition (FIG. 5).

Regarding claims 6 and 20, Schaefer discloses that a proximal end of the member is electrolytically detachable from a delivery device (Column 6 lines 38-56).

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Regarding claims 14 and 28, Schaefer discloses a method of occluding a selected site, the method comprising accessing the site with a delivery apparatus; deploying the vaso-occlusive device from the delivery apparatus into the selected site of the vessel in a manner allowing a portion of the vaso-occlusive device to substantially assume its relaxed serpentine shape and form along a surface of the vessel at the site (Column 6 line 38-Column 7 line 11).

3. Claims 1, 5, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,136,015 to Kurz et al.

Regarding claims 1 and 15, Kurz discloses a vaso-occlusive device comprising a member having a length, at least a portion of the length having a planar serpentine shape (FIG. 1-3) and not forming a three-dimensional spiral loop when the member is in a relaxed condition, wherein at least a portion of the serpentine shape comprises a curvilinear segment having a non-uniform curvature.

Regarding claims 5 and 19, Kurz discloses that the proximal and distal portions have a serpentine shape, and the middle portion is a linear shape in the relaxed condition (FIG. 1-3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7, 8, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. '101.

Schaefer discloses the claimed invention except for the particular dimensions of the member's length and amplitude. It would have been an obvious matter of design choice to change the member's length and amplitude, since such a modification would have involved a mere change in the size of a component and there is no stated reason and solves no particular problem for the particular length and amplitude claimed (see paragraph 17). A change in size is generally recognized as being within the level of ordinary skill in the art. The length and amplitude of the Schaefer device can be adapted for different sizes of aneurysms and would work equally well when made larger or smaller to suit the aneurysm.

6. Claims 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. '101 in view of Kurz et al. '015.

Schaefer discloses the claimed invention except for the distal end of the member having a J-shaped tip. Kurz teaches that the J-shaped tip is provided on the distal end of the device to prevent the device from puncturing the tissue, to prevent the coil from migrating into the artery, and to prevent coil realignment (Column 3 lines 21-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaefer with a J-shaped tip in order to prevent the device from puncturing the tissue, to prevent the coil from migrating into the artery, and to prevent coil realignment.

7. Claims 10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. '101 in view of U.S. Patent No. 5,749,894 to Engelson.

Schaefer discloses the claimed invention except for the plurality of fibers attached to the member. Engelson teaches that fibers are attached to the member to enhance the thrombogenicity of the device (Column 3 lines 22-25). It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to provide the device of Schaefer with the fibers of Enfelson in order to increase the thrombogenicity of the device.

8. Claims 11, 12, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. '101 in view of U.S. Patent No. 5,382,259 to Phelps et al.

Schaefer discloses the claimed invention except for a polymeric fiber wrapped around the surface of the member. Phelps teaches that a polymeric fiber is wrapped around the member to enhance the ability of the coil to fill the space within the vasculature and to increase embolic and tissue growth around the member (Column 1 lines 40-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaefer with a polymeric fiber wrapped around its member in order to enhance the ability of the member to fill the space and to increase embolic and tissue growth.

9. Claims 13 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. '101 in view of U.S. Patent No. 5,582,619 to Ken.

Schaefer discloses the claimed invention except for the member being stretch resistant. Ken teaches the use of a stretch resistant member to prevent the coil from stretching while it is being positioned, repositioned, or removed from the vasculature (Column 1 lines 9-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaefer with a stretch resistant member in order to prevent the member from stretching when it is being moved in the vasculature.

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Response to Arguments

10. Applicant's arguments filed January 20, 2004 have been fully considered but they are not persuasive.

11. Applicant argues that Schaefer et al. '101 does not disclose a device with non-uniform curvature. Schaefer does disclose many loops of different sizes (FIG. 1). This is considered to be non-uniform curvature. Applicant also argues that Schaefer does not disclose a method wherein a portion of the device substantially assumes "its relaxed serpentine shape along a surface of the vessel at the site." Schaefer discloses that the device has intimate contact with the surface of the aneurysm as it is deployed into the aneurysm (Column 7 lines 4-34). Therefore, the rejection over Schaefer et al. '101 is proper.

12. Applicant argues that Kurz et al '015 does not disclose a serpentine shape. Figures 1-5 of Kurz show serpentine shapes. These shapes are considered to be serpentine because they have many curves or turns. Therefore, the rejection over Kurz et al. '015 is considered to be proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

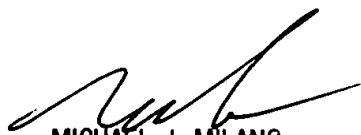
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731

JRB
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